

EXHIBIT I

Konstantin Walmsley, M.D.

1 IN THE UNITED STATES DISTRICT COURT
 2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
 3 AT CHARLESTON
 4 - - -

5 IN RE: ETHICON, INC., : MASTER FILE NO.
 6 PELVIC REPAIR SYSTEM : 2:12-MD-02327
 PRODUCTS LIABILITY : MDL 2327
 7 LITIGATION :
 : JOSEPH R. GOODWIN
 8 : U.S. DISTRICT JUDGE

 9 SHERRY FOX and ROY FOX, JR. :
 Plaintiffs, :
 10 :
 v. : CASE NO.
 11 : 2:12-CV-00878
 JOHNSON & JOHNSON, INC. and :
 12 ETHICON, INC., :
 Defendants. :
 13 - - -

14 March 23, 2016
 15 - - -

16 Oral deposition of KONSTANTIN
 17 WALMSLEY, MD taken pursuant to notice, was held at
 18 the law offices of Mountainside Hospital, 1 Bay
 Avenue, Montclair, New Jersey, beginning at 12:23
 19 p.m., on the above date, before Ann Marie Mitchell,
 a Federally Approved Certified Realtime Reporter,
 20 Registered Diplomate Reporter and Notary Public.
 21 - - -

22 GOLKOW TECHNOLOGIES, INC.
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Konstantin Walmsley, M.D.

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2 I N D E X
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5 Testimony of: KONSTANTIN WALMSLEY, MD
6 By Mr. Oliveira 5, 73
7 By Mr. Casperson 71

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24 (Exhibit Fox-Walmsley-4 was retained
25 by the witness and is not attached to the
transcript.)

Konstantin Walmsley, M.D.

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Konstantin Walmsley, M.D.

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(Deposition Exhibit No.

3

Fox-Walmsley-1, Amended Notice to take

4

video deposition of Konstantin Walmsley,

5

and Deposition Exhibit No. Fox-Walmsley-2,

6

Rule 26 Expert Report of Konstantin

7

Walmsley, MD, was marked for

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identification.)

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KONSTANTIN WALMSLEY, MD, after having

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been duly sworn, was examined and

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testified as follows:

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14

EXAMINATION

15

- - -

16 BY MR. OLIVEIRA:

17

Q. I started to say good morning,

18

Dr. Walmsley, but I realized it's afternoon now.

19

Good afternoon. How are you doing?

20

A. I'm well.

21

Q. We met earlier?

22

A. We did.

23

Q. I believe I told you I represent

24

Ethicon in this case involving Sherry Fox. And so I

25

guess I'm a little confused, because my

1 understanding, you're here to offer case-specific
2 opinions today; is that correct?

3 A. Yes, sir.

4 Q. Okay. Because I also saw that you
5 had some general opinions in your report?

6 A. In the Fox report?

7 Q. Yes.

8 A. General opinions that are applicable
9 to the case, I suppose, would be the way I would
10 interpret it.

11 Q. Okay. That's fine.

12 A. Yeah.

13 Q. But you're not here to offer -- well,
14 let me ask you this: The general opinions, you say
15 they're related to the facts of this particular case
16 and that's why you've offered them?

17 A. Yes, sir.

18 Q. Okay. Let me show you what's been
19 marked as Fox-Walmsley -- I'll just call it Exhibit
20 Number 1. I'm not going to say that every time.

21 I'll relate to you it's a notice to
22 take your deposition.

23 Do you see that?

24 A. Yes, sir.

25 Q. Have you seen that before?

1 A. I have.

2 Q. There's a Document A that's attached
3 to it that has asked you to bring a number of
4 documents.

5 Did you bring any documents
6 responsive to those?

7 A. I did.

8 Q. And what did you bring?

9 A. I brought -- actually brought
10 Ms. Fox's IME report, and I also brought a list of
11 my prior testimonies.

12 Q. Had you produced that IME report
13 before? Does your lawyer have a copy?

14 A. He received a copy yesterday evening.
15 Yes, sir.

16 Q. Okay. Because I was going to say, I
17 don't think I've seen one. Let's -- I'm sorry.

18 MR. CASPERSON: We also have some
19 stuff here that -- that's another copy of the IME
20 report, and there's also a thumb drive which has
21 some prior depositions of Dr. Walmsley, some prior
22 reports that he's done in some other pelvic mesh
23 cases, and some invoices, including an invoice for
24 this case.

25 MR. OLIVEIRA: Okay. I hate these

1 things because I always lose them.

2 BY MR. OLIVEIRA:

3 Q. Well, let's start with the IME
4 report.

5 Let's mark that as -- I've already
6 got one premarked as 2. So we'll mark that one as
7 3.

8 - - -

9 (Deposition Exhibit No.
10 Fox-Walmsley-3, Fox, Sherry Encounter
11 Summary, 12/04/2015, was marked for
12 identification.)

13 - - -

14 BY MR. OLIVEIRA:

15 Q. And then it looks like you also have
16 a binder --

17 A. Yes, sir.

18 Q. -- that you brought.

19 And can you tell me what's in that
20 binder?

21 A. This binder is a table of contents,
22 articles and materials that I've relied upon in part
23 to create my opinion. There's some deposition
24 testimony in here as well as medical records. And
25 then some Rule 26 expert reports.

1 Q. And we'll go ahead and mark that as
2 Exhibit Number 4.

3 - - -

4 (Deposition Exhibit No.
5 Fox-Walmsley-4, Binder, was marked for
6 identification.)

7 - - -

8 THE WITNESS: I should also mention,
9 if I may, in addition I added some abstracts, three
10 separate abstracts to the binder as well.

11 BY MR. OLIVEIRA:

12 Q. And what abstracts are those?

13 A. These are abstracts that specifically
14 talk to suburethral slings and autologous fascial
15 slings. They're abstracts from three separate
16 articles.

17 Q. Is this something that you just
18 pulled in the last couple of days, or --

19 A. In the last week or so as I was
20 getting ready for the deposition, I thought it might
21 be helpful just to look at some of the materials
22 that Dr. Irwin in part relied upon to form her
23 report.

24 Q. Did you -- you also produced a report
25 in this case?

Konstantin Walmsley, M.D.

1 A. Yes, sir.

2 Q. I'm going to show you what we'll
3 mark -- that we have marked. It's been marked as
4 Exhibit Number 2 and ask you if that's your report?

5 A. Yep. This is my report.

6 Q. When was -- when did you draft that
7 report?

8 A. Oh, I would reckon two months ago,
9 give or take.

10 Q. I don't see a date on it.
11 Do you date your reports?

12 A. I have in the past. Sometimes I do.
13 Sometimes I do not.

14 Q. Do you see anywhere in this report
15 where it's been dated?

16 A. It's not been dated in this report.

17 Q. And so you say you believe you
18 prepared it two months ago?

19 A. Yes. Roughly.

20 Q. Do you have any idea, do you have any
21 indication, any e-mails or anything that would
22 clarify when you sent this report to your attorney?

23 A. I do, yeah.

24 Q. You do. Do you have them with you?

25 A. It's in my computer downstairs. I

1 can --

2 Q. On a break I may ask you to go look
3 for the date of -- the date I guess you drafted and
4 the date that you sent it to your lawyer?

5 A. I'm happy to.

6 Q. And while you're down there, if you
7 could also do it for the Ridgley case, I would
8 appreciate it.

9 A. I would be happy to.

10 Q. There may be a date on that one. I'm
11 not sure there is.

12 When were you first retained by the
13 plaintiffs to provide or to serve as an expert in
14 this case?

15 A. In the late summer/early fall of
16 2015.

17 Q. And who was it that contacted you?

18 A. Mr. Casperson.

19 Q. And what did he ask you to do in this
20 case?

21 A. He asked me to review medical records
22 relating to the care of Sherry Fox.

23 Q. And did he send you medical records?

24 A. Yes, sir.

25 Q. And do you recall which medical

1 records those were?

2 A. They're listed in the report and also
3 in the binder, yes.

4 Q. Have you ever been retained by
5 Mr. Casperson or his firm in any previous case?

6 A. I have been, yes.

7 Q. You have been?

8 A. Yes, sir.

9 Q. When was the first time they retained
10 you in a case?

11 A. 2014.

12 Q. Was it involving the mesh litigation?

13 A. Yes, sir.

14 Q. Do you recall which case it was?

15 A. One was Boston Scientific, the other
16 is Bard.

17 Q. No previous Ethicon cases prior to
18 this, these two cases?

19 A. No, not with Mr. Casperson, no.

20 Q. How about with any other plaintiffs'
21 firm? Have you been hired by other plaintiffs'
22 firms to provide expert testimony in any mesh cases?

23 A. I have, yes.

24 Q. What other firms are you dealing with
25 right now?

1 A. There's one case relating to a
2 Prolift case. That was actually a med mal case.
3 And then I also served as an expert witness for
4 Boston Scientific and Bard for Perdue & Kidd.

5 Q. When you say you served as an expert
6 for Boston Scientific, you weren't retained by
7 Boston Scientific. Correct?

8 A. No, sir. I was retained -- it was in
9 that litigation.

10 Q. But you were retained by the Perdue
11 firm from Houston?

12 A. Yes, sir.

13 Q. What was the first year, I guess,
14 when were you first retained to do any -- provide
15 any expert testimony in any of these mesh cases?

16 A. That would be 2013.

17 Q. Do you know how many cases, mesh
18 cases, you've been retained on to date?

19 A. I would give a fairly reliable
20 estimate of eight to ten.

21 Q. Do you think it could be more?

22 A. No.

23 Q. Do you know how much you've billed in
24 all those cases?

25 A. All combined?

1 Q. Yes.

2 A. Probably in the order of 50- to
3 \$75,000.

4 Q. You said you generated an invoice,
5 and I got your attorney handing me a thumb drive,
6 and I can't open it right now.

7 But do you know how much you've
8 billed on the Fox case?

9 A. I'd have to give you a ballpark
10 estimate, in the range of 6- to \$7,000.

11 Q. And how many hours does that involve?

12 A. That involves about 13 hours, 13-plus
13 hours of work.

14 Q. Does that include preparation for
15 this depo?

16 A. No. No, sir.

17 Q. How much time have you spent
18 preparing for this deposition today?

19 A. I received some -- well, I reviewed
20 Irwin's report, and I also reviewed some additional
21 records, so probably in the order of four to six
22 hours. I have it written down, but I haven't billed
23 yet for this.

24 Q. Have you -- prior to I guess
25 providing expert testimony in the mesh cases, and I

1 think you told us about one malpractice case, have
2 you served as an expert before in other litigation?

3 A. I have, yes, sir.

4 Q. About how many cases?

5 A. I'd guess I'd have to ask, when you
6 say serving as an expert witness, are you speaking
7 in terms of these going to testimony or just all the
8 cases I've given --

9 Q. Just where you've been retained to
10 provide expert testimony.

11 A. I probably review -- as far as giving
12 prior testimony, probably in the order of 15 to 20.

13 Q. And how many times have you been
14 deposed?

15 A. As an expert witness, I've been
16 deposed perhaps ten times.

17 Q. So then -- and I forgot to bring this
18 up in the beginning. So then you know the basic
19 rules of a deposition. We have this lovely young
20 lady over here taking down everything we say, and if
21 we speak over each other, we'll drive her crazy. So
22 I'll do my best not to interrupt you, and if you can
23 wait until I finish my question, it will help her
24 out a lot.

25 A. Yes, sir.

1 Q. Okay. Thanks. And you you've done
2 fine so far. It's something I neglected to say
3 earlier.

4 If you can turn to your report, which
5 is Exhibit Number 2, I believe.

6 You have that in front of you?

7 A. Yes.

8 Q. Did you include all of your opinions
9 in this report that you intend to testify about in
10 this case?

11 A. Yes.

12 Q. Okay. And as you sit here today,
13 have you received any additional information that
14 you didn't have when you prepared this report?

15 A. Yes.

16 Q. And what additional information is
17 that?

18 A. Some additional medical records
19 relating to physical therapy received by the patient
20 and some additional depositions, one of Dr. Irwin's
21 and the other, Dr. Thames.

22 Q. What deposition did you see of
23 Dr. Irwin's?

24 A. Dr. Irwin provide -- I'm sorry. It
25 wasn't a deposition. Excuse me. It was a Rule 26

1 report. Pardon. As was Dr. Thames a Rule 26
2 report.

3 Q. Was it a Rule 26 report regarding
4 this case, regarding the Fox case?

5 A. Yes.

6 Q. And you received those all after you
7 did your report?

8 A. Yes.

9 Q. Now that you've gotten this
10 additional -- and let me ask you, is there any other
11 additional information that you've gotten that you
12 didn't have when you drafted this report?

13 A. No.

14 Q. Is any of this additional
15 information, is that going to require you to
16 supplement your report or revise your report in any
17 way?

18 A. No.

19 Q. I believe you just told me you
20 performed a physical examination of Mrs. Fox in this
21 case?

22 A. Yes, sir, I did.

23 Q. And when did that take place?

24 A. That occurred on December 4, 2015.

25 Q. Did you request that?

1 A. Mr. Casperson requested that.

2 Q. And where did you examine her?

3 A. I examined her in my office.

4 Q. Your office here in New Jersey?

5 A. Yes, sir.

6 Q. So she flew up to -- for that visit?

7 A. Yes.

8 Q. Let me ask you, other than -- well,
9 strike that.

10 Let me ask you, what did you review
11 before drafting your report, your final report?
12 What did you rely on to draft your report?

13 A. So I relied upon the medical records
14 that are stated in the report. There were a handful
15 of articles that I used as references in terms of
16 forming my opinion. I had the IFU for the TVT
17 device that dated back to the time that it was
18 implanted. And also an informed consent document
19 produced by the AMA.

20 There were several depositions that I
21 relied upon, that of Mrs. Fox, Dr. Warner, Dr.
22 Villa-Olvera, Dr. Haverkorn and then of course my
23 IME as well.

24 Q. And the medical records that you said
25 you've relied on, are all those contained in the

1 binder that's been marked as -- I believe as -- did
2 we mark them Exhibit 4, I believe?

3 A. Yes. And the answer to that is yes.

4 Q. How many studies did you rely on?

5 A. Many.

6 Q. They're all listed there? Do you
7 have them numbered or --

8 A. They're all -- they're all provided
9 here numerically and with a bibliography, and there
10 are a total of over 20 of them.

11 And I guess as we were alluding to
12 before, this is a case-specific report. I've read
13 hundreds of articles that relate to pelvic mesh
14 and -- both in the world of slings and pelvic organ
15 prolapse repair. But these were the ones of
16 significance that I really relied upon in the
17 formation of my opinion here.

18 Q. And I'm looking at your binder, and
19 it looks like it has 34 tabs in it?

20 A. Correct. Yeah.

21 Q. Besides -- is each one tabbed
22 separately, or are they --

23 A. The articles are all tabbed
24 separately, and the articles run from tab 3 to tab
25 22.

1 Q. And then after tab 22, do you have an
2 index there?

3 A. Yes, sir.

4 After tab 22, there are four
5 depositions, 23 to 26. The medical records
6 encompass tabs 27 to tab 31. And then there are
7 three additional documents, two Rule 26 expert
8 reports that I alluded to before, and then 34 is
9 photos of the pathology specimen from Mrs. Fox's
10 mesh explant.

11 Q. Is there anything other than what
12 you've showed us in your binders, anything -- and
13 then I guess the IME report, is there anything else
14 that you relied on in formulating your opinions for
15 your report?

16 A. No, sir.

17 MR. CASPERSON: Objection to form.
18 BY MR. OLIVEIRA:

19 Q. Have you ever implanted midurethral
20 slings in patients?

21 A. I have, yes.

22 Q. Do you know how many?

23 A. I could give you a ballpark estimate.
24 I've been in practice since 2004. Between 2003 and
25 2004, during my fellowship, I implanted roughly 50

1 implants. And then in practice, I implanted --
2 during the early part of my career, I probably
3 implanted between 30 and 40 implants a year. Now
4 I'm implanting about 20 or so per year. So I would
5 give an estimate of several hundred. I mean,
6 certainly over 250 and probably more on the order of
7 300 to 400.

8 Q. Okay. Have you ever implanted a TVT
9 device like the one that was implanted in Mrs. Fox
10 in this case?

11 A. I have.

12 Q. And when did you -- when was the last
13 time that you did one of those?

14 A. Primarily during my fellowship years.

15 Q. And did you receive training, I
16 guess, from Ethicon, some kind of training before
17 you began implanting their products?

18 A. Actually, most of my training
19 occurred both during my residency and then in my
20 fellowship with a Dr. Steven Kaplan.

21 I did receive training in private
22 practice on the TVT SECUR device. But as far as the
23 classic TVT device, I learned primarily during my
24 training years.

25 Q. And you say you still implant

1 midurethral slings?

2 A. I do.

3 Q. And 20 to 25 a year?

4 A. Roughly, yes.

5 Q. Do any of those include Ethicon
6 products or --

7 A. No. No, sir.

8 Q. What primarily, what products do you
9 use?

10 A. Three main products, a Bard product,
11 a Coloplast product and occasionally an AMS product.

12 Q. Have you ever taken a part or have
13 you ever done any studies yourself involving the
14 treatment of stress urinary incontinence surgically
15 or the surgical treatment, I guess, of stress
16 urinary incontinence?

17 A. I've not published any articles in
18 that arena, no.

19 Q. How about any studies involving the
20 TVT product that was used in this case?

21 A. No, sir.

22 Q. I looked at your reliance list or the
23 studies I guess that you looked at earlier. And one
24 of the studies I noticed you listed in your list is
25 the Nilsson study?

1 A. Yes.

2 Q. And that was a study done by
3 Dr. Nilsson in 2013. Correct?

4 A. Yes, sir.

5 Q. And it's called the "Seventeen years'
6 follow-up of the tension-free vaginal tape procedure
7 for female stress urinary incontinence"?

8 A. Yes.

9 Q. And it looks like, since you listed
10 it, I assume, then, that you considered that as
11 part of your -- considered that study in formulating
12 your opinions in this case?

13 A. Yes.

14 Q. That study, you would agree with me
15 that study was done by a reputable author in a
16 peer-referenced journal. Correct?

17 MR. CASPERSON: Form.

18 THE WITNESS: Yes.

19 BY MR. OLIVEIRA:

20 Q. And did you review any other studies
21 that showed that polypropylene-based midurethral
22 slings like the TVT have low compliance -- or low
23 complications rate?

24 Let me rephrase that because I kind
25 of jumped ahead.

1 A. Uh-huh.

2 Q. This study I guess shows -- the
3 results were that it showed that polypropylene-based
4 midurethral slings had low complications rate.
5 Correct?

6 A. The Nilsson study did demonstrate a
7 fairly low complication rate.

8 Q. And they showed that they were safe
9 and reliable?

10 MR. CASPERSON: Form.

11 THE WITNESS: I mean, those terms
12 were not used in the report, but his conclusion was
13 that it was a durable procedure with a high
14 satisfaction rate.

15 BY MR. OLIVEIRA:

16 Q. When you said a low complications
17 rate, do you remember what the complications rate
18 was? Or do you have that in front of you?

19 A. Well, of his report, a little under
20 80 percent were reachable via telephone interview.
21 So it's -- you know, given the fact that over
22 20 percent were not really followed up on, I think
23 that's a fair critique of the follow-up. These were
24 retrospective phone-based interviews of which only
25 half the patients were visiting the clinic. So the

1 20 of them, over 20 were lost to follow-up. 12 were
2 interviewed via phone. So, in essence, only half
3 the patients really were examined in a comprehensive
4 enough fashion that I think that that would be a way
5 to really look at complications.

6 MR. OLIVEIRA: Objection, form.

7 BY MR. OLIVEIRA:

8 Q. My question is, what was the
9 complication rate? What was the rate, the result
10 that they reached that this study showed?

11 MR. CASPERSON: Object to the form of
12 the question.

13 THE WITNESS: You know, this report
14 didn't necessarily look at complications as much as
15 success or cure rates, to my mind. So it's hard to
16 answer that question.

17 BY MR. OLIVEIRA:

18 Q. So let me ask you this.

19 A. Yes.

20 Q. What was the success rate, I guess?

21 A. He -- the conclusion was that over
22 90 percent of the women were objectively continent,
23 and 87 percent were significantly cured or improved
24 of the patients who were available to be questioned.

25 Q. Doctor, would you agree with me that

1 stress urinary incontinence is a life -- or can be a
2 life-altering condition for women?

3 A. Yes.

4 Q. And for many women with this
5 condition, it can seriously restrict their everyday
6 activities?

7 A. Yes.

8 Q. Exercising, working, if it's serious
9 enough. Correct?

10 A. I agree.

11 Q. And I think you testified previously
12 in other cases that polypropylene mesh --
13 polypropylene-based mesh slings like the TVT are the
14 standard of care for midurethral slings. Correct?
15 Do you recall that?

16 A. I recall saying something to that
17 effect.

18 Q. Do you recall also saying previously
19 that polypropylene slings like the TVT are the gold
20 standard for surgical treatment of SUI?

21 A. No. That I specifically recall
22 refuting, actually.

23 Q. Okay. So you don't think you said
24 that in a previous deposition?

25 A. If I did, I think what I was probably

1 alluding to was the fact that they're still done.

2 And for most of us, it is considered the standard of
3 care. But I recall, frankly, disputing the concept
4 of gold standard.

5 Q. Fair enough. In 2002 when Mrs. Fox
6 had a TVT implanted to treat SUI, would you agree at
7 that time it was the standard of care for surgical
8 treatment of SUI?

9 MR. CASPERSON: Objection to form.

10 THE WITNESS: No, I would not.

11 BY MR. OLIVEIRA:

12 Q. In 2002 it would not be the standard
13 of care?

14 A. Not in my practice and training at
15 that time.

16 Q. Can you cite me to I guess any
17 studies that would say -- that would show that it
18 was not considered the standard of care in 2002 when
19 Mrs. Fox had hers implanted?

20 A. I could.

21 Q. And what studies are those?

22 A. Part of my training at Cornell
23 involved mentorship under a Jerry Blaivas, who is a
24 major proponent of the autologous fascial sling.

25 In 2002, over 80 percent of the

1 slings that I implanted were of the autologous
2 fascial variety. Dr. Blaivas, even as late as 2011,
3 has published articles in which he opines that the
4 autologous fascial sling is the gold standard of
5 care for the treatment of stress urinary
6 incontinence.

7 MR. OLIVEIRA: Object to form.

8 BY MR. OLIVEIRA:

9 Q. But my question was when Mrs. Fox had
10 this implanted in 2002, would the TVT that was
11 implanted, would it be considered the standard of
12 care -- I didn't say the gold standard -- for
13 surgical treatment of SUI?

14 A. No.

15 Q. And you believe, then, that the
16 implanting physician, then, violated the standard of
17 care by implanting that device in 2002?

18 A. No. I wouldn't say that.

19 Q. Okay. Then how do you recognize that
20 you -- when you make the statement that it was not
21 the standard of care?

22 A. I would reconcile that by stating
23 that oftentimes we provide surgical care where we
24 utilize techniques or devices that may not
25 necessarily be recognized as either the standard of

1 care or the gold standard of care.

2 Q. But your position as you sit here
3 today is that in 2002, implanting the TVT device
4 would not have been the standard of care?

5 A. Not yet.

6 Q. When did it become the standard of
7 care?

8 A. That's a difficult question to ask,
9 but I would opine that it became the standard of
10 care probably in the latter part of the first decade
11 of the 21st century, in the 2005 to 2007 arena.

12 Q. Were people -- I mean, were
13 gynecologists and urogynecologists implanting --
14 obviously there were people implanting midurethral
15 slings prior to that time. Correct?

16 A. Urologists too, yes.

17 Q. Okay. And so it was an acceptable
18 procedure prior to 2005-2006?

19 A. Yes.

20 Q. And it was one that was used widely
21 in your profession for the treatment of SUI?

22 A. Starting to at that time, yes.

23 Q. Mark the next exhibit.

24 - - -

25 (Deposition Exhibit No.

1 Fox-Walmsley-5, AUGS Position Statement on
2 Mesh Midurethral Slings for Stress Urinary
3 Incontinence, was marked for
4 identification.)

5 - - -

6 BY MR. OLIVEIRA:

7 Q. I'm going to hand you Exhibit
8 Number 5, which I will tell you is the AUGS and SUFU
9 position statement on mesh midurethral slings for
10 stress urinary incontinence.

11 A. Thank you.

12 Q. Are you familiar with this statement?

13 A. I am.

14 Q. And so the jury's clear, SUI -- or
15 AUGS stands for Advanced -- I'm sorry, the
16 Association of Urogynecologists Society? Or is that
17 right? Or Advanced Urogynecology --

18 A. I think it's the Association of
19 Urogynecological Surgeons.

20 Q. Surgeons. Thank you.

21 A. Yes, sir.

22 Q. And then is SUFU it looks like is the
23 Society of Urodynamics, Female Pelvic Medicine &
24 Urogenital Reconstruction; is that correct?

25 A. Yes, sir.

1 Q. And are these two reputable,
2 recognized societies?

3 A. Yes, sir.

4 Q. The top statement in the paper -- let
5 me see where I can find this. My other copy had it
6 highlighted.

7 There's a portion in there, I'll read
8 it to you, it says, "The polypropylene mesh
9 midurethral sling is the recognized worldwide
10 standard of care for the surgical treatment of SUI."

11 It goes on to say, "The procedure is
12 safe, effective, and has improved the quality of
13 life for millions of women."

14 MR. CASPERSON: Is it under
15 conclusions?

16 MR. OLIVEIRA: It might be. Let me
17 see.

18 THE WITNESS: Yes.

19 BY MR. OLIVEIRA:

20 Q. Did you find it?

21 A. Yes. It's in two separate locations,
22 but yes.

23 Q. Where is the first location that you
24 find it?

25 A. Page 2, bold, bold number 3, it

1 states, "Polypropylene mesh midurethral slings are
2 the standard of care for the surgical treatment of
3 SUI."

4 And then your other comment is the
5 first page -- is the first sentence of the
6 conclusion section on page 3.

7 MR. OLIVEIRA: Okay. Let's go off
8 the record for a second.

9 MR. CASPERSON: Okay. Off the
10 record.

11 - - -

12 (A recess was taken from 12:53 p.m.
13 to 12:54 p.m.)

14 - - -

15 BY MR. OLIVEIRA:

16 Q. So, Doctor, I think when we were --
17 when I previously asked you about that statement,
18 you said I guess you found it on page 2 and it looks
19 like on number 3?

20 A. Yes.

21 Q. So it says, "Polypropylene mesh
22 midurethral slings are the standard of care for the
23 surgical treatment of SUI and represent a great
24 advance in the treatment of this condition for our
25 patients."

1 Do you agree with that statement?

2 MR. CASPERSON: Form.

3 THE WITNESS: I think in part I do,
4 yes.

5 BY MR. OLIVEIRA:

6 Q. And then I think the second part that
7 talks about the procedure is safe -- well, let me
8 ask you this because you said in part. I should ask
9 you.

10 A. Yeah.

11 Q. What part do you not agree with?

12 A. I think it's become the standard of
13 care for the surgical treatment of SUI. I think it
14 is a mild to moderate advance in the treatment of
15 this condition for our patients, in part because it
16 has shown -- certain elements have been shown to be
17 superior to the other treatments that we offer.
18 However, there are potential complications that can
19 arise from the use of mesh for pelvic slings -- or
20 for urethral slings, excuse me.

21 Q. Doctor, isn't it true there's also
22 complications with nonmesh procedures for the
23 treatment of SUI?

24 A. Yes. Certainly.

25 Q. I think the second part says, "The

1 procedure is safe, effective and has improved the...
2 life for millions of women."

3 And you said you found that I guess
4 on the third page or --

5 A. On the third page, the first sentence
6 of the conclusion states it has helped millions of
7 women, although I don't see the safe, effective part
8 of that comment.

9 Q. I think the next sentence has it,
10 where it says "acknowledged safety and efficacy it
11 has created in an environment for a much larger
12 number of women."

13 A. Right.

14 Q. My question is, do you agree with
15 that statement?

16 MR. CASPERSON: Objection, form.

17 THE WITNESS: I don't.

18 BY MR. OLIVEIRA:

19 Q. And why don't you agree with that
20 statement?

21 A. You know, in part because there are
22 questions as to the safety of slings and because the
23 efficacy over longer periods of time isn't
24 necessarily as high as one would expect it to be,
25 certainly, for example, to call it a gold standard

1 type of procedure.

2 Q. What about the Nilsson 17-year study
3 that we talked about earlier? Doesn't that show
4 that over a long period of time, it was effective?

5 A. I think in his study, of 50 percent
6 or so of patients that he actually was able to have
7 physical contact with, it showed a high rate of
8 success.

9 Q. Well, you gave me your reasons I
10 guess why you question the safety and efficacy, but
11 the first statement, it says it "has helped millions
12 of women with SUI regain control of their lives."

13 Would you agree with that?

14 A. I think that's a true comment, yes.

15 Q. Let's look at, I guess, the second
16 page now.

17 The first statement says,
18 "Polypropylene material is safe and effective as a
19 surgical implant."

20 Do you agree with that statement?

21 MR. CASPERSON: Objection, form.

22 THE WITNESS: Is that comment number
23 2?

24 BY MR. OLIVEIRA:

25 Q. I think it's number 1.

1 "Polypropylene material is safe and effective as a
2 surgical implant."

3 A. Yes. I think that's a nebulous
4 statement, so I think it could be worded
5 differently.

6 Q. Worded as is, would you agree with
7 that?

8 A. I would say polypropylene material is
9 safe and effective as a surgical implant for the
10 repair of hernias, for example, for example, for the
11 repair of abdominal wall hernias or for an
12 application in sacrocolpopexy, but I would question
13 that comment in the context of pelvic mesh.

14 Q. You've told us you continue to use
15 polypropylene materials in the treatment of SUI, and
16 you continue to implant them. Correct?

17 A. This is true.

18 Q. And so you do that even though you're
19 questioning the safety and effectiveness of it?

20 A. You know, in 2016, I'm able to
21 counsel my patients differently about sling surgery.
22 And there's a reason I implant less slings than I
23 did five, ten years ago.

24 Q. But you still implant them?

25 A. I do.

1 Q. And you haven't quit implanting
2 surgical mesh, have you?

3 A. I have not, no.

4 Q. What about, do you agree that --
5 well, let me ask you this: You do implant
6 polypropylene materials -- you currently still do
7 it, so would you agree with me, then, that you
8 wouldn't do it if it wasn't a safe and effective
9 alternative for the treatment of SUI, would you?

10 MR. CASPERSON: Objection, form.

11 THE WITNESS: I'm sorry. Could you
12 rephrase that question? I'm sorry.

13 BY MR. OLIVEIRA:

14 Q. No, it's okay. It's my fault.

15 You've told us that you still implant
16 polypropylene mesh. And so is it fair to say, then,
17 that you believe that it's safe for your patients to
18 have these implants and that it is safe -- that it's
19 effective for the treatment of SUI?

20 A. I believe that it's -- after an
21 informed consent has been given for some of my
22 patients, it's a safer and more effective form than
23 other treatments.

24 Q. And then number 3 says,
25 "Polypropylene mesh midurethral slings are the

1 standard of care for the surgical treatment of SUI
2 and represents a great" advantage "in the treatment
3 of this condition for our patients."

4 Do you see that?

5 A. I do.

6 Q. And do you agree with that statement?

7 MR. CASPERSON: Objection, form.

8 THE WITNESS: It says "great advance"
9 instead of "advantage."

10 BY MR. OLIVEIRA:

11 Q. I'm sorry.

12 A. I think I answered the question
13 before that I didn't agree with it in whole.

14 Q. And remind me again what your -- what
15 you disagreed with.

16 A. My comment is that -- my comment
17 before was that I felt that it was -- the
18 terminology "great advance" I think kind of
19 overstates the utility of slings, and certainly in
20 the armamentarium to treat stress urinary
21 incontinence, it's become a very commonly utilized
22 procedure. Whether it's truly a great advance in
23 the treatment of this condition, I think to some
24 degree remains to be seen.

25 Q. Have you ever belonged to AUGS or

1 SUFU?

2 A. I've not.

3 Q. Do you practice with other
4 urogynecologists or urologists who belong to either
5 of those organizations?

6 A. I do.

7 Q. Are you familiar also with the
8 American Urogynecological Association, the AUA,
9 position statement on the use of vaginal mesh for
10 surgical treatment of SUI?

11 A. I've seen it before.

12 Q. And I think -- and I don't have a
13 copy of that, but do you agree with the statement it
14 makes in there that extensive data exists to support
15 the use of polypropylene mesh suburethral slings for
16 the treatment of female SUI with minimal morbidity
17 compared to alternative surgeries?

18 MR. CASPERSON: Objection to form.

19 THE WITNESS: I agree for the most
20 part with the exception of the minimal morbidity.

21 BY MR. OLIVEIRA:

22 Q. So you disagree that there's minimal
23 morbidity?

24 A. I think the morbidity occurs in a
25 small subset of patients; however, that morbidity

1 can be more than minimal for those patients.

2 Q. It goes on to say that advantages
3 include shorter operation time. I'll break it down
4 so that I can give you a chance to...

5 Do you agree with the statement that
6 one of the advantages include a shorter operation
7 time?

8 A. Yes, sir.

9 Q. I guess reduced surgical pain?
10 MR. CASPERSON: Objection, form.

11 THE WITNESS: Not necessarily, but
12 possibly.

13 BY MR. OLIVEIRA:

14 Q. Reduced hospitalization?
15 MR. CASPERSON: Objection, form.

16 THE WITNESS: Yes.

17 BY MR. OLIVEIRA:

18 Q. And then I guess another advantage
19 they list is voiding dysfunction?

20 MR. CASPERSON: Objection to form.

21 BY MR. OLIVEIRA:

22 Q. Reduced voiding dysfunction I guess
23 would be --

24 A. In the short term, yes. In the long
25 term, no.

1 Q. It goes on to say, mesh-related
2 complications can occur following polypropylene
3 sling replacement, but the rate of complications is
4 acceptably low.

5 Do you agree with that statement?

6 MR. CASPERSON: Objection, form.

7 THE WITNESS: I think from a
8 quantitative statement, that's a true comment.

9 MR. OLIVEIRA: Doctor, if you don't
10 mind, let's take a little break, and we'll move into
11 phase 2.

12 THE WITNESS: Thank you.

13 - - -

14 (A recess was taken from 1:04 p.m. to
15 1:21 p.m.)

16 - - -

17 BY MR. OLIVEIRA:

18 Q. If you could I'd ask you to turn to
19 your report, which we have marked as -- I believe as
20 Exhibit 2 in this case.

21 A. Yep.

22 Q. It looks like the first four or five
23 pages of your report are kind of background
24 information and mentions, I guess, the medical
25 records and depositions that you reviewed, along

1 with the medical literature and other documents that
2 you reviewed. Correct?

3 A. Yes.

4 Q. And then you do -- at some point you
5 have a clinical history where you -- it looks like a
6 little chronology where you list a number of
7 different things in her medical history, I guess,
8 that you believe were significant?

9 A. Yes, sir.

10 Q. Then after that, you get into what
11 looks like the couple of general opinions?

12 A. Yes, sir.

13 Q. And then five case-specific opinions
14 or -- yes, it looks like it's five. Is that
15 correct?

16 A. Yes.

17 Q. So let me ask you about your first
18 opinion.

19 Your first general opinion, you state
20 there at the bottom that it's your opinion "the IFU
21 for the TVT in 2002 was not sufficient to enable
22 informed consent from the patient."

23 What do you base that on?

24 A. I base that on my clinical experience
25 with TVT and, for that matter, other polypropylene

1 mesh slings and the IFU that I reviewed that dated
2 back to the time when this sling was implanted.

3 Q. And what do you believe is missing
4 from this IFU that you would put in it?

5 A. Well, there are a lot of potential
6 complications that were not mentioned in the IFU
7 that I've listed in my report.

8 Q. Doctor, would you agree with me that
9 generally, that IFUs typically don't include every
10 potential adverse reaction or complication? Isn't
11 that correct?

12 A. Not necessarily.

13 Q. So you believe that they should have
14 every adverse reaction or every possible reaction to
15 the product?

16 A. I think they should have the majority
17 of them, the ones that are the most likely to occur.

18 For those that are case-report like
19 complications or case-report like findings, I would
20 agree with you, those don't necessarily need to be
21 in the IFU. But certainly the ones that you see
22 with even some regularity or occasional regularity
23 should be mentioned.

24 Q. So tell me, then, which ones do you
25 believe should be in there?

1 A. Well, first, as far as complications
2 to be mentioned, mesh contraction would be one.
3 Dyspareunia. Mesh shrinkage. Scar plate formation.
4 The difficulty in removing mesh.

5 Q. Are those all the ones you feel
6 should be in there?

7 A. That's the majority of them, yes.

8 Q. You would agree with me that a doctor
9 not only has to rely on the IFU for explaining, I
10 guess, the adverse reactions and possible side
11 effects to a plaintiff.

12 Would you agree with that?

13 A. I'm sorry. Could you repeat that
14 question?

15 Q. Well, can doctors also rely, don't
16 they also rely on their experience, their clinical
17 experience in implanting mesh or in this particular
18 case, to rely on -- in providing an informed consent
19 to the plaintiff?

20 A. I think that's a true comment, yes.

21 Q. And do you do that in your practice?

22 A. I do.

23 Q. And do you include things when you go
24 over your informed consent that are not necessarily
25 included in the IFU?

1 A. To some degree.

2 Q. Do you believe that most doctors do
3 that?

4 A. Well, it's hard for me to comment on
5 that. I'm not necessarily sure what all doctors do,
6 but I think that's the standard of care.

7 Q. The standard of care is that they
8 should --

9 Well, let me ask you this: Is it
10 your understanding -- is the IFU intended to be a
11 substitute for a surgeon's knowledge or expertise in
12 a case?

13 A. In terms of providing clinical
14 consent you mean?

15 Q. Yes.

16 A. No. I think there are two elements
17 to the informed consent: One provided by the IFU,
18 and to your point, I think the other provided by a
19 surgeon's experience, assuming he or she has
20 clinical experience.

21 Q. And the IFU is not intended to be a
22 substitute for a surgeon's responsibility to
23 adequately counsel a patient regarding the risk and
24 benefits of treatment options. Correct?

25 A. I don't think it's a substitute, but

1 I think it's something that's a necessary adjunct.
2 I mean, for example, for someone who's performing
3 their first 10 to 15 slings, I would imagine those
4 individuals would rely in large part on the IFU to
5 counsel patients appropriately.

6 Q. But wouldn't they also rely on any
7 training they received?

8 A. True.

9 Q. And wouldn't most people, most
10 doctors that are doing those first 10 or 15 slings
11 would have learned from somebody else or would have
12 been trained by somebody else prior to them
13 inserting or implanting those slings. Correct?

14 A. I would hope so.

15 Q. I lost my place in your report.

16 And then in general opinion number 2,
17 it looks like you're -- what is your general opinion
18 number 2? I'm not sure --

19 A. General opinion number 2 is that
20 "Safer alternatives designs and procedures existed
21 in 2002 that have a lesser risk of erosion and
22 dyspareunia with substantially equivalent efficacy."

23 Q. Which procedures in particular are
24 you referring to?

25 A. The autologous fascial sling.

1 Q. What else?

2 A. Primarily that procedure in my
3 experience, but certainly nonsynthetic mesh-based
4 repairs were alternatives.

5 Q. But the autologous procedure doesn't
6 come without risk either, does it?

7 A. That's correct.

8 Q. I mean, it has risks?

9 A. That's correct.

10 Q. And it has complications?

11 A. True.

12 Q. And hasn't it also proven to be less
13 effective than midurethral slings in treating stress
14 urinary incontinence?

15 A. Not in my practice, no.

16 Q. Have you seen studies that indicate
17 that midurethral slings have a higher success rate
18 in treating stress urinary incontinence?

19 A. I've seen some studies that provide
20 that opinion.

21 Q. What else do you -- you say "safer
22 alternatives designs and procedures existed in
23 2002."

24 Other than the autologous sling that
25 you told us about, what else existed back then?

1 A. There were biological graft slings
2 that were available at that time using porcine
3 dermis, for example. The Burch colposuspension
4 procedure was available.

5 Q. Have you ever used any of those
6 procedures?

7 A. I have. Not -- well, let me amend
8 that. The Burch colposuspension procedure I did in
9 my training, but I did not utilize that in my
10 private practice.

11 Q. Why is that?

12 A. You know, because I started utilizing
13 the autologous fascial sling at the tail end of my
14 training, and that replaced my utilization of the
15 Burch colposuspension procedure.

16 Q. And what other -- and you mentioned,
17 I guess -- what was the other procedure that you
18 mentioned was safer?

19 A. The use of a biological graft sling
20 using basically porcine dermis, pigskin.

21 Q. Did you ever use that in your
22 practice?

23 A. I did.

24 Q. Do you use it?

25 A. I don't use it any more because it's

1 not marketed anymore, in fact.

2 Q. When was the last time you used that?

3 A. 2008, 2009, in that range.

4 Q. Let me ask you, also you say "safer
5 alternatives designs."

6 You're not going to offer any
7 opinions here today on -- you're not being offered
8 as a design expert, are you?

9 A. I'm not, no.

10 Q. Okay. And so other than these
11 procedures that you just listed, what other
12 procedure have you not told us about that is safer?

13 A. Well, one procedure that would be
14 safer would involve urethral bulking, the use of
15 either collagen or another substance to bulk up the
16 external sphincter of the female urethra.

17 Q. Do you use that procedure?

18 A. Occasionally I do.

19 Q. Do you use it in your practice today?

20 A. I do.

21 Q. Anything else you haven't told us
22 about?

23 A. With regards to what I was using back
24 in 2002, no.

25 Q. And those are all the general

1 opinions that you've given that relate to, I guess,
2 Mrs. Fox in this case, just those two?

3 A. The only one other thing I think is
4 worth mentioning is -- dates back -- or goes back to
5 the general opinion number 1 with regards to the
6 IFU, which is the, in my opinion, inappropriate use
7 of the term "transitory."

8 Q. And why is it inappropriate?

9 A. Because in the 2000 -- in the IFU
10 that would have been available in 2002, the word
11 "transitory" was used in two contexts, one being
12 "transitory local irritation at the wound site" and
13 the next being "transitory foreign body response may
14 occur."

15 And as stated in the report, the use
16 of transitory really defines a condition that is
17 temporary, when, in fact, a thing such as foreign
18 body response and irritation at the wound site are
19 quite the contrary. They're chronic events.

20 Q. And so you would disagree with that
21 because of the reasons you just stated?

22 A. Yes, sir.

23 Q. Anything else with regards to number
24 1, general opinion number 1?

25 A. No, sir. That's it.

1 Q. Then we go to your case-specific
2 opinions, and your first one is that "Mrs. Fox
3 suffered vaginal sling extrusion, contraction, scar
4 plate formation, and failure of the TVT to
5 incorporate, as a result of the physical properties
6 of the TVT device."

7 Let's start with the first one.

8 A. Okay.

9 Q. How did you determine she had
10 extrusion?

11 A. Based on my review of the medical
12 records, and to some degree the deposition of
13 Dr. Olvera specifically.

14 Q. And what in particular did you see in
15 Dr. Olvera's report that led you to believe there
16 was extrusion?

17 A. She describes an edge of the TVT
18 located near the urethra that she specifies as an
19 erosion.

20 Q. Anything else that supports your
21 belief that there was an extrusion?

22 A. Other than her identifying mesh
23 within the vagina, no.

24 Q. Did you see any evidence of erosion
25 in any medical records?

1 MR. CASPERSON: Object to the form.

2 Let me clarify the basis. Because
3 the records go back and forth, I think we need to
4 clarify that for the record, which is which.

5 THE WITNESS: I mean, I think --
6 yeah. I think of erosion and extrusion as occurring
7 along a continuum. There are some doctors that
8 believe that erosion really specifies mesh eroding
9 into an organ, for example, the bladder or the
10 rectum. There are others that would identify
11 exposure, if you will, of mesh into the vagina as an
12 extrusion event. I think an extrusion is a minor
13 erosion. And an erosion is a major extrusion, if
14 you will.

15 BY MR. OLIVEIRA:

16 Q. Okay.

17 A. So I think of them as really one and
18 the same with an extrusion essentially being a minor
19 erosion event.

20 Q. My question, I guess, is, do you see
21 in any of her medical records where any of her
22 doctors said there was an erosion -- they described
23 it as an erosion as opposed to an extrusion?

24 A. The doctor says two different things.
25 Dr. Haverkorn uses extrusion more commonly, and

1 Dr. Olvera initially states an erosion of the edge
2 of the TVT near the urethra when, in fact, I think
3 it's semantically one and the same.

4 Q. So your belief it's one and the same,
5 but you recognize that some
6 urologists/urogynecologists believe there is a
7 difference, and some doctors believe there is a
8 difference?

9 A. I think that's a fair comment.

10 Q. Let's go on, because you've got some
11 other -- we've just covered extrusion.

12 You also mention contraction.

13 A. Yes, sir.

14 Q. What's your basis for finding
15 contraction?

16 A. I think mesh contraction in the case
17 of Sherry Fox was primarily identified not only by
18 her clinical course but also by Dr. Haverkorn's
19 findings.

20 Q. That mesh contraction was?

21 A. Correct.

22 Q. And that Dr. Haverkorn, you're saying
23 in her findings and her report, found mesh
24 contraction?

25 A. I think her medical records indicated

1 that, and then she supported that in her deposition.

2 Q. Do you have that in front of you,
3 where she says that mesh contraction?

4 A. Yes. It's at the bottom of where you
5 see my specific opinion on contraction and
6 shrinkage. I state that "Mrs. Fox's TVT contracted
7 post implantation. Dr. Haverkorn testified
8 generally regarding mesh contraction or shrinkage as
9 follows," where she's asked in her deposition about
10 mesh shrinkage. And she describes mesh shrinkage as
11 something that occurs.

12 Q. Something that occurs, but does she
13 say that it occurred in Mrs. Fox?

14 A. She does.

15 Q. Okay.

16 A. Yeah, on page 40 of her deposition,
17 there is language that supports that concept where
18 the mesh was present and was taut.

19 Q. What about on the -- you also in your
20 case-specific, you mentioned the failure of the TVT
21 to incorporate.

22 A. Correct.

23 Q. On what basis do you make that
24 statement?

25 A. Primarily on the basis of there being

1 a mesh erosion or extrusion, as the case may be,
2 where de facto one is seeing a piece of mesh that is
3 not incorporated into the host tissues.

4 Dr. Villa-Olvera in her records
5 visually, but also in her deposition, describes
6 clear white mesh on the surface of the vagina that
7 was not incorporated into any of the host tissues,
8 Mrs. Fox's vaginal tissues specifically.

9 Q. And I'm sorry. She says that in her
10 deposition?

11 A. Yes, sir.

12 Q. Can you point that out to me? Is
13 that something that you've listed in your report --

14 A. It's in my report under "D. Failure
15 to Incorporate." And that is further along, I
16 think, where you're looking at currently.

17 After the picture of the removed
18 portion of the TVT mesh, there's comments related to
19 the deposition.

20 Q. Okay.

21 A. Yes, sir.

22 Q. Okay. Where she describes it as not
23 being incorporated into the --

24 A. Yeah.

25 Q. Okay. Anywhere else that you saw

1 that?

2 A. Other than the medical records and
3 what was stated in the deposition, no.

4 Well, I shouldn't say that. I stand
5 corrected. Dr. Haverkorn's operative report speaks
6 to a mesh exposure which would support a failure to
7 incorporate.

8 Q. Let's turn to your case-specific
9 opinion number 2.

10 You state, "Mrs. Fox's extrusion in
11 2012 was caused by the physical properties of the
12 TVT -- specifically, the mechanically cut edge of
13 the TVT."

14 What do you mean -- what do you mean
15 there? What's your basis for saying that?

16 A. My basis for saying that, at least
17 from a case-specific standpoint, speaks to the
18 nature of her extrusion/erosion, namely, the fact
19 that the mesh extrusion or erosion, if you will,
20 occurred at the edge of the TVT sling.

21 In addition, I do have some
22 understanding based on my training and experience
23 that there is a difference between -- there's a
24 difference in terms of causes of exposure or
25 erosion. For example, occasionally I've seen mesh

1 erosion or extrusion events occur in the context of
2 a fraying or roping of the mesh. So at the time of
3 surgery, I'll find that myself.

4 In this particular instance, given
5 the location of the erosion, it being at the edge, I
6 would conclude it was based on the mechanically cut
7 edge of the TVT.

8 MR. OLIVEIRA: Object to the form.

9 BY MR. OLIVEIRA:

10 Q. Did you see any evidence of
11 degradation of the mesh or have you seen any
12 evidence anywhere in any of the reports of
13 degradation of the mesh or...

14 MR. CASPERSON: Object to the form.

15 THE WITNESS: Not in Mrs. Fox's case
16 I did not.

17 BY MR. OLIVEIRA:

18 Q. Any evidence of chronic inflammation?

19 A. I believe so, yes.

20 Q. Where did you see that?

21 A. Well, I think the premise to this
22 answer lies in the fact that when a suburethral
23 polypropylene sling is placed, part of the
24 properties of its success, if you will, delve into a
25 chronic inflammatory process whereby a scar plate is

1 generated that allows the mesh to have or provide a
2 backboard of support to prevent incontinence.

3 Certainly looking at the picture of
4 the mesh explant, there's a significant amount of
5 fibrotic tissue in addition to the exposed part of
6 the mesh that would support the concept of chronic
7 inflammation.

8 Q. Did you consider vaginal atrophy as a
9 possible cause of Mrs. Fox's extrusion in 2012?

10 A. I did.

11 Q. And did you rule that out?

12 A. Yes, sir, I did.

13 Q. Is vaginal atrophy something that
14 could cause or lead mesh to extrude in a patient?

15 A. It could certainly increase the
16 complication of that, yes.

17 Q. And then your case-specific opinion
18 number 3 is that her "vaginal pain and dyspareunia
19 (from July 2011 to March 2012) was caused by her
20 sling extrusion, contraction of the TVT device, and
21 scar plate formation."

22 Is that your third opinion?

23 A. Yes, sir.

24 Q. Isn't it true that dyspareunia and
25 pain following TVT surgery are pretty uncommon?

1 MR. CASPERSON: Objection, form.

2 THE WITNESS: They're fairly
3 uncommon.

4 BY MR. OLIVEIRA:

5 Q. Have you seen the Tommaselli 2015
6 systematic review and analysis?

7 A. Is this the Cochran review that
8 you're referring to?

9 Q. I think this one was Tommaselli. I'm
10 not sure if Cochran was a co-author, but it's a
11 2015 -- I'll tell you this: This study found that
12 only 13 patients out of 3,974 who had had
13 suburethral slings implanted had persistent or
14 chronic pain.

15 Have you seen that study?

16 A. I may be aware of that study, but off
17 the top of my head, I'm not fully aware of it.

18 Q. And I'll tell you, it was only 13 out
19 of 3,974 patients, and that's a rate of 0.3 percent.

20 Would you agree that's a pretty low
21 rate of dyspareunia and pain following TVT surgery?

22 MR. CASPERSON: Objection, form.

23 THE WITNESS: Based on his
24 experience, that's certainly lower than what I see
25 in my practice and what I would counsel patients

1 towards.

2 BY MR. OLIVEIRA:

3 Q. Can you point me to any studies that
4 you've done that would -- that you conducted
5 yourself that would show a higher rate?

6 A. Well, my experience is just based on
7 my clinical practice using TVT.

8 Q. But you haven't published any studies
9 or you haven't conducted any level 1 -- or you
10 haven't taken part in any level 1 studies that
11 studied this issue, have you?

12 A. I've not.

13 Q. Okay.

14 A. I'm not fully familiar with the study
15 that you've quoted to me, but...

16 Q. What is Lichens sclerosis?

17 A. Well, Lichens sclerosis is a
18 dermatological condition that entails the
19 development of whitish plaques that can typically
20 cause an itching type of a discomfort on the
21 external genitalia amongst other locations.

22 Q. Is it something that can become a
23 serious problem for women?

24 A. It can become a serious problem for
25 women and men.

1 Q. For men too?

2 A. Yeah.

3 Q. Is that something that could be
4 responsible for or could cause the uncomfortableness
5 that Mrs. Fox notes, I guess, in sitting down for
6 periods of time? Could that be a reason?

7 A. That is sometimes described as being
8 an issue for Lichens sclerosis, yeah.

9 Q. Is Lichens sclerosis, isn't one of
10 the side effects also dyspareunia?

11 A. There are instances where there is
12 external dyspareunia with Lichens sclerosis, yes.

13 Q. What about her diagnosis of
14 superimposed vulvodynia, are you familiar with that?

15 MR. CASPERSON: Objection.

16 THE WITNESS: Yes.

17 BY MR. OLIVEIRA:

18 Q. Did you consider that in considering
19 her vaginal pain and dyspareunia?

20 A. I did, yes, sir.

21 Q. And did you rule that out also?

22 A. I did, yes, sir.

23 Q. Let's go to your case-specific
24 opinion number 4.

25 It looks like your opinion there is

1 that she "continues to have dyspareunia presently"?

2 A. Correct.

3 Q. And what do you base that on?

4 A. In large part on my independent exam,
5 but also based on -- well, I should say because of
6 presently, I would say it's in large part on the
7 basis of my medical exam which was performed on
8 December 4, 2015.

9 Q. And this is the report that you
10 handed me earlier that, I guess, we've marked as
11 Exhibit Number 3, it looks like?

12 A. Yes.

13 Q. What was the result of that exam?
14 What did you find?

15 A. Well, in part, besides taking a
16 clinical history during which time she explained to
17 me that she had dyspareunia, on questioning her and
18 talking about the type of dyspareunia she had, she
19 related her dyspareunia to in part being an internal
20 dyspareunia, where on exam I could palpably
21 reproduce pain upon palpation somewhat deep in the
22 vagina but up in what's called the right vaginal
23 sulcus of the vagina, which is the location of
24 her -- near the location of her erosion event or
25 extrusion event, as the case may be.

1 Q. What else in her physical exam led
2 you to believe she continues to have dyspareunia?

3 A. I think to be fair, you know, we have
4 to premise the answer or I have to premise the
5 answer by saying dyspareunia, which is discomfort
6 with intimacy, is premised on attempts at intimacy.
7 And to be fair, because of her dyspareunia, she's
8 only attempting to have intercourse on a somewhat
9 infrequent basis.

10 That being said, in discussing with
11 her her dyspareunia, she attributes the dyspareunia
12 to a specific location within her vaginal area.

13 On my exam, when I examined her, at
14 least, her -- the majority of her pain on exam
15 occurred in an area of vagina near the right vaginal
16 sulcus, internally in an area where I could palpate
17 scar tissue and an area where her mesh or perhaps at
18 least an edge of mesh may have been located from her
19 prior surgery with Dr. Haverkorn.

20 Q. Did you recommend any course of
21 treatment for her after your examination?

22 A. The one thing I did recommend for her
23 was based primarily on her having an elevated
24 post-void residual and talked about ceasing her
25 VESIcare and considering Kegel exercises and/or

1 biofeedback to help her with her incontinence.

2 Q. Mrs. Fox also suffered from stress
3 urinary incontinence prior to the implantation of
4 the mesh. Correct?

5 A. Yes, sir.

6 Q. That was the reason for having the
7 mesh implant?

8 A. Yes.

9 Q. And do you remember her description
10 of her SUI?

11 A. Based on my report, her complaint was
12 of losing urine -- at least when she presented to
13 Dr. Warner initially or at the women's clinic, I
14 should say, complained of losing urine for the
15 previous year when jumping or sneezing.

16 Q. This had become a serious problem for
17 her. Correct?

18 MR. CASPERSON: Object to the form.

19 THE WITNESS: It was serious enough
20 for her to seek out treatment, yes, sir.

21 BY MR. OLIVEIRA:

22 Q. It was a life-altering condition
23 because she couldn't exercise anymore without
24 urinating?

25 A. Or sneeze, for that matter.

1 Q. Or sneeze, for that matter.

2 Are you aware that it appears she got
3 complete relief from her SUI for at least ten years?

4 A. This is a true comment, yes.

5 Q. Dr. Walmsley, also in your report,
6 you note that a -- I guess a photograph of the
7 portion of the TVT explanted from Mrs. Fox depicts
8 scar tissue that had become adhered to the TVT as a
9 result of a chronic foreign body response.

10 What evidence do you have or what
11 basis do you have to support that statement?

12 MR. CASPERSON: What page are you on?

13 MR. OLIVEIRA: I have to find it. It
14 was in my notes, but I know it's in his report.

15 I think the scarring is under -- I'm
16 sorry. We may have to jump back to 3.

17 MR. CASPERSON: Are you talking about
18 the picture, scar plate?

19 MR. OLIVEIRA: Yeah.

20 MR. CASPERSON: Okay.

21 MR. OLIVEIRA: That's on page --

22 MR. CASPERSON: That's a good
23 question. It's not numbered.

24 MR. OLIVEIRA: It's not numbered.

25 MR. CASPERSON: It's the picture of

1 the scar plate, Doctor. That's what he's referring
2 to.

3 MR. OLIVEIRA: Yeah, and I just saw
4 it. I passed it up. Yeah, that's the difficulty.
5 That's why I didn't have it on my --

6 MR. CASPERSON: I should say the
7 picture of what we allege to be a scar plate.

8 THE WITNESS: Oh, right.

9 BY MR. OLIVEIRA:

10 Q. Did you find that?

11 A. I did, yes.

12 Q. Okay. And so my question was, on
13 what basis you made the statement -- let's see.

14 MR. OLIVEIRA: I'm sorry. Can you
15 read back my question, because I lost my place?

16 - - -

17 (The court reporter read the
18 pertinent part of the record.)

19 - - -

20 THE WITNESS: There are a couple of
21 elements to the answer.

22 The first is, I've experienced
23 patients of mine who have had mesh erosion or
24 extrusion events where I've explanted mesh. And
25 unlike in this case where it was submitted to a

1 pathology off campus, I've submitted it to
2 pathologists here in the hospital and actually
3 looked at the slides with my colleagues and seen
4 chronic inflammation and a foreign body response.
5 That's a fairly classic response to polypropylene
6 mesh.

7 In addition, I've also in my
8 bibliography have used reports or read reports that
9 describe the response to placement of polypropylene
10 mesh, which inherently is designed to create an
11 inflammatory response and scar tissue in order to
12 provide its desired effect.

13 Obviously in this instance, the
14 scarring perhaps led to a negative outcome insofar
15 as there was a subsequent complication requiring
16 removal.

17 BY MR. OLIVEIRA:

18 Q. In fact, I think you testified, scar
19 tissue formation is a kind of necessary, I guess,
20 for the -- to provide, I guess, integration through
21 the mesh pores. It's a necessary part of the TVT
22 procedure?

23 A. That's correct.

24 Q. What's your position -- what's your
25 personal position -- and I believe you testified

1 before that you have excised or you've removed mesh
2 yourself before. Correct?

3 A. I have. Yes, sir.

4 Q. What's your position regarding
5 partial excision as opposed to total recision or
6 removal?

7 A. I think the majority of revision or
8 excision of mesh procedures are partial, in part
9 because it's extremely difficult to remove all of
10 the mesh. That ends up requiring a significant
11 amount of dissection to do so. And sometimes one
12 can resolve mesh complications with partial
13 excisions.

14 Q. And do you perform partial excisions?

15 A. The only mesh excisions I've done
16 have been partial, in fact.

17 Q. And finally, your last opinion is
18 that "Mrs. Fox's future prognosis as it relates to
19 her pelvic pain, dyspareunia, and voiding
20 dysfunction is guarded."

21 What's your basis for saying that?

22 A. Well, I think there are several
23 things. First off, there's still residual pelvic
24 mesh within her body. And there will be ongoing
25 fibrosis and chronic inflammation relating to that.

1 Even if the mesh were to be removed in its entirety,
2 that would be an extensive type of surgical
3 procedure, probably restricted to an academic type
4 of center.

5 Of interest to me during the IME was
6 the amount of discomfort she had when I palpated the
7 area of mesh excision, which supports to me that
8 even in the process of removing mesh, when one is
9 trying to resolve a problem, there are inherent
10 complications of scarring and fibrosis with the
11 partial excision itself.

12 Q. And what evidence -- when you talk
13 about voiding dysfunction, what evidence of voiding
14 dysfunction have you seen in the medical records?

15 A. In her particular instance, besides
16 the recurrence of her incontinence, it appears that
17 her incontinence now is not just stress
18 incontinence, it's what we called mixed urinary
19 incontinence, which is a combination of stress
20 incontinence and urgency urinary incontinence.
21 Typically we see that in patients with overactive
22 bladder. She was treated with VESicare. When I saw
23 her in my office in December, she was on VESicare,
24 which is an anticholinergenic drug used to treat
25 overactive bladder.

1 She had had some partial resolution
2 with the VESicare with relation to her urgency, but
3 not only was the urgency not completely ameliorated,
4 but she had an elevated post-void residual. It was
5 quite high in my office, which supports to me,
6 number one, that the VESicare is providing perhaps
7 too much of a bladder relaxation effect, number one.
8 And number two, that she is incomplete emptying,
9 which could be related to scarring from her sling
10 procedure or possibly might be related to the
11 VESicare effect or, thirdly, could be related to
12 some sort of functional disorder of the bladder.

13 MR. OLIVEIRA: Object to the form.

14 BY MR. OLIVEIRA:

15 Q. We've gone through your two general
16 opinions and your five specific opinions in this
17 case.

18 As we sit here today, do you have any
19 other opinions that you haven't already mentioned or
20 you haven't testified about or that are not
21 contained in your report?

22 A. No, sir.

23 MR. OLIVEIRA: I'm going to pass the
24 witness. I know your attorney probably has a few
25 questions, and then I'll -- I'll pass if you have a

1 few questions. If not...

2 MR. CASPERSON: We'll reserve for
3 trial.

4 MR. OLIVEIRA: Okay. Then I will
5 actually recess and just let me look through my
6 notes and make sure. I was going to do that while
7 you were questioning to save some time. I'll do
8 that, so just give me a few minutes.

9 MR. CASPERSON: Off the record.

10 - - -

11 (A recess was taken from 2:03 p.m. to
12 2:03 p.m.)

13 - - -

14 (Deposition Exhibit No.
15 Fox-Walmsley-6, PT Progress Note, was
16 marked for identification.)

17 - - -

18 EXAMINATION

19 - - -

20 BY MR. CASPERSON:

21 Q. Dr. Walmsley, I'm handing you what's
22 marked as Exhibit 6 to your deposition.

23 These are the physical therapy
24 records related to Ms. Fox.

25 Does that appear to be correct?

1 A. Yes, sir.

2 Q. Is this something that you received
3 after your original Rule 26 report was sent?

4 A. Yes.

5 Q. Have you had a chance to review
6 those?

7 A. I did review these, yeah.

8 Q. Were there any findings in those
9 physical therapist records that are significant in
10 forming your opinions here today?

11 A. Yes.

12 Q. What are those findings that you
13 think carry some significance as part of helping you
14 form your opinions?

15 A. Well, I mean, first off, she
16 continues to have pelvic and vaginal pain.

17 Secondly, the physical therapist
18 during her exam, while performing a digital exam of
19 the vaginal space, was able to identify discomfort
20 and tenderness in the right aspect of her vagina,
21 consistent with what I found in my IME exam.

22 Q. Do you believe that to be the same
23 area that you palpated during your IME with Ms. Fox?

24 MR. OLIVEIRA: Objection, form.

25 THE WITNESS: Yeah. The same exact

1 area. Yes.

2 MR. CASPERSON: I'll pass the
3 witness.

4 MR. OLIVEIRA: Let me look at those
5 records real quick.

6 - - -

7 (A recess was taken from 2:05 p.m. to
8 2:07 p.m.)

9 - - -

10 EXAMINATION

11 - - -

12 BY MR. OLIVEIRA:

13 Q. Doctor, Exhibit Number 6 that your --
14 Mr. Casperson just questioned you about, these are
15 physical therapy records from a -- it looks like a
16 physical therapy clinic in San Antonio?

17 A. Yes, sir.

18 Q. And did it appear to you that -- I
19 guess these are the -- this is just the first
20 segment of treatment that she's going to be getting
21 or first segment of physical therapy?

22 A. I'm not sure how many segments of
23 physical therapy she's going to receive, but I know
24 she's getting a series of them, yes.

25 Q. But this doesn't seem to represent a

1 complete -- that she's completed her whole physical
2 therapy regime here, has she?

3 A. I don't believe so, no.

4 Q. So there's a possibility that after
5 she completes however many sessions she's scheduled
6 for -- it looks like it's physical therapy one time
7 a week for 12 weeks -- wouldn't that be a better
8 indication of whether the physical therapy has been
9 helpful?

10 A. I think it would be helpful for her
11 to complete, yeah, her physical therapy and then to
12 reassess that area.

13 Q. And wouldn't that be, I guess, a more
14 accurate assessment of what her condition is after
15 she completes the physical therapy?

16 A. I mean, I hate to be a pessimist. I
17 don't believe there will be much improvement, but
18 there might be some, without question.

19 Q. Did you see -- going back to the
20 voiding dysfunction, prior to the mesh removal, did
21 you see any mention anywhere in the medical records
22 of voiding dysfunction or urinary incontinence?

23 A. I did not.

24 Q. Did you also see that Mrs. Fox
25 reported to Dr. Haverkorn that the SUI, I guess,

1 she's currently -- has returned but it's not
2 bothersome and that the urgency/frequency is only
3 occasional?

4 MR. CASPERSON: Object to the form.

5 THE WITNESS: Her last appointment on
6 April 17th states that she has occasional overactive
7 bladder symptoms with occasional stress
8 incontinence. And at that time she's not on
9 VESIcare.

10 BY MR. OLIVEIRA:

11 Q. So that suggests that it hasn't
12 returned to the level it was prior to the surgery,
13 the implantation in 2002. Correct?

14 A. As far as stress urinary
15 incontinence, yes.

16 Q. Yes. And that you also are aware
17 that Mrs. Fox has testified that she had complete
18 relief from SUI for the ten years that she had the
19 implant?

20 A. Correct.

21 MR. OLIVEIRA: Doctor, I think those
22 are all the questions I have regarding Mrs. Fox.
23 Thank you for your time.

24 THE WITNESS: Thank you.

25 (Witness excused.)

1 (Deposition concluded at
2 approximately 2:11 p.m.)
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I HEREBY CERTIFY that the witness was
duly sworn by me and that the deposition is a true
record of the testimony given by the witness.

It was requested before completion of
the deposition that the witness, KONSTANTIN
WALMSLEY, MD, have the opportunity to read and sign
the deposition transcript.

ANN MARIE MITCHELL, a Federally Approved
Certified Realtime Reporter, Registered
Diplomate Reporter and Notary Public

(The foregoing certification of this
transcript does not apply to any reproduction of the
same by any means, unless under the direct control
and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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Konstantin Walmsley, M.D.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby
certify that I have read the foregoing pages, 1 -
81, and that the same is a correct transcription of
the answers given by me to the questions therein
propounded, except for the corrections or changes in
form or substance, if any, noted in the attached
Errata Sheet.

KONSTANTIN WALMSLEY, MD DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

Notary Public

Konstantin Walmsley, M.D.

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